

DOI: <https://dx.doi.org/10.18203/2320-1770.ijrcog20213467>

Original Research Article

A prospective randomized comparative study of rapidly absorbing polyglactin 910 versus chromic catgut for episiotomy repair at tertiary care hospital Bikaner, Rajasthan

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Received: 25 June 2021

Accepted: 19 July 2021

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ABSTRACT

Background: The aim of our study was to compare rapidly absorbing polyglactin 910 with chromic catgut as a suture material for episiotomy repair, in relation to post episiotomy complications and maternal morbidity.

Methods: This prospective, randomized, comparative study of rapidly absorbing polyglactin 910 versus chromic catgut for episiotomy repair was conducted in the department of obstetrics and gynaecology, PBM hospital, associated with Sardar Patel medical college Bikaner, Rajasthan.

Results: RAPG-910 was associated with significantly lesser analgesic dose requirement for pain relief than chromic catgut. Use of chromic catgut was associated with a higher incidence of hematoma formation, wound gaping, need of re-suturing of wound and need of re-admissions for management of post-episiotomy complications than RAPG-910 although, the difference was statistically insignificant. RAPG-910 was associated with better wound condition & healing as compared to chromic catgut.

Conclusions: To conclude, rapidly absorbing polyglactin 910 was better than chromic catgut in relation to post episiotomy complications and maternal morbidity with a significantly lesser incidence and severity of post episiotomy pain, lesser dose of analgesia required, lesser wound gaping and infection, better wound healing, faster suture reabsorption.

Keywords: Episiotomy, Pain, Catgut, Polyglactin 910

INTRODUCTION

Episiotomy is a surgical incision on the perineum carried out by an obstetrician or skilled birth attendant during labour to enlarge the vaginal opening.¹ It is also known as perineotomy. Episiotomy is one of the most commonly performed procedures in obstetrics. It was introduced in the 18th century to prevent perineal tears, future sexual dysfunction and the incontinence that resulted from vaginal births.² Now a days, there are various types of suture materials available which can be used for episiotomy repair. Out of these, polyglactin 910 and chromic catgut are commonly used.

Catgut suture is used for all surgical procedures including general closure, ophthalmic, orthopedics, obstetrics/ gynaecological and gastrointestinal surgery. It is absorbed faster in patients with cancer, anemia and malnutrition. It is also absorbed faster when used in the mouth and the vagina, due to the presence of microorganisms. Polyglactin 910 is the material of choice across specialties for soft tissue approximation e.g. ophthalmic procedures, mucosal closures, skin closure, dental surgery, orthopedic surgery. Due to its quick absorption rate, polyglactin 910 should not be used where extended approximation of tissue is required as in cardiovascular and neurological tissues.

Studies have shown that synthetic suture materials like polyglactin 910 have less postnatal morbidity compared to catgut but the risk of increased need for suture removal. This shortcoming was addressed by irradiated polyglactin 910 which gets absorbed faster than the standard polyglactin 910. Size of suture material most frequently used size is 2-0 vicrylrapide, followed by 1-0 and 2-0 coated vicryl. Selection of appropriate suture material for use in episiotomy repair has been a topic of debate and study among the practitioners.³ So, this study has been designed to study two different suture materials, namely rapidly absorbing polyglactin 910 and chromic catgut, in relation to post episiotomy complications and maternal morbidity like perineal pain, analgesic requirement, in duration, hematoma formation, wound gaping, wound infections, wound healing, formation of scar tissue and dyspareunia; when used for episiotomy repair.

METHODS

Study design, setting and duration

This prospective, randomized, comparative study of rapidly absorbing polyglactin 910 versus chromic catgut for episiotomy repair was conducted in the department of obstetrics and gynaecology, PBM hospital, associated with Sardar Patel medical college Bikaner, Rajasthan from 1 July 2019 to 30 June 2020.

Study sample and sampling method

Women admitted in labor room, having uneventful intrapartum period and delivering vaginally with episiotomy and fulfilling the inclusion criteria, were enrolled in the study after ruling out the exclusion criteria. Sampling was done using systematic random sampling method.

Inclusion criteria

Inclusion criteria for current study were; women with vaginal deliveries assisted by episiotomy and were willing to participate in the study and follow up, age group (between 19 to 35 years) and free from any present systemic illness like diabetes mellitus, renal disease, immunocompromised conditions like HIV/AIDS, leukemia that could have affected wound healing and study results.

Exclusion criteria

Exclusion criteria for current study were; women who had vaginal delivery without need of episiotomy, deliveries by LSCS, or episiotomy assisted vaginal deliveries; but were not willing to participate in the study and / or follow up, women having systemic illness at the time of study e.g. diabetes mellitus, renal disease, hepatitis B, immunocompromised conditions like HIV/AIDS, malignancy, on steroids, psychiatric illness;

that could have affected wound healing and study, women having perineal or vaginal tears, extension of the episiotomy, severe preeclampsia, severe anaemia, intrauterine foetal demise, features of premature rupture of membranes, chorioamnionitis, septicemia and the cases which were handled outside before admission with increased risk of sepsis and possible complications and instrumental deliveries.

Sample size

During study period of 1 July 2019 to 30 June 2020, total 498 cases (of episiotomy assisted vaginal delivery after applying the inclusion & exclusion criteria) were taken, follow up was done. First 150 cases of each group who had completed their follow up till 6 weeks atleast were selected. Thus, two study groups group A and group B (150 cases in each) were made and total sample size 300 was taken.

Case selection and data collection

Proper counselling was done and well informed oral & written consent was taken. Particulars of cases were noted. A detailed personal history was taken about onset of labor pain, bleeding or leaking per vaginum, excessive weight gain, swelling of feet, epigastric pain, oligouria and blurring of vision in the present pregnancy.

Data analysis

To collect the required information from eligible cases, pre-tested and semi-structured proforma was used. Data was systematically analysed by using appropriate statistical test and software as required and $p < 0.05$ was considered as statistically significant. The descriptive data is presented as number and percentage with mean and standard deviation, wherever required. The chi-square test has been used for analysing the categorical data. The unpaired t test is used to compare between the mean of study groups.

RESULTS

This study sample comprised of a total of 300 cases randomized into two groups of 150 each. In group- A, rapidly acting polyglactin 910 was used for episiotomy repair; and in group B, chromic catgut was used. Use of chromic catgut was associated with a higher severity of post episiotomy pain, as mean values of VAS at 48 hours (5.46 ± 0.62 v/s 5.86 ± 0.71), day 7-10 (0.73 ± 0.12 v/s 1.20 ± 0.18) and 6 weeks (0.14 ± 0.05 v/s 0.23 ± 0.08) were more in group B than group A. The difference in severity of pain between both study groups was statistically significant ($p < 0.05$). While at 24 hours, severity of pain was almost similar in both study groups; as the difference between mean values of VAS (5.84 ± 0.77 v/s 5.93 ± 0.83) was statistically insignificant ($p > 0.05$). In first 24 hours of post episiotomy, 96.7% cases in group A and 98.7% cases in group B needed analgesics for pain relief. While,

between 24-48 hours; 94.7% cases of group-A and 97.3% cases of group- B required analgesics for pain. Numbers of cases with need of analgesics for pain relief at ≤ 24 hours and between 24-48 hours were almost similar in both the study groups. As the difference was statistically

insignificant ($p>0.05$). At day 7-10; 41.3% cases in group A and 64.7% cases in group B required analgesics for pain relief. While, at 6 weeks; 3.3% cases of group A and 9.3% cases of group B required analgesics.

Table 1: Socio-demographic details.

Variables	Group A (RAPG - 910)	Group B (chromic catgut)	P value
Age (years)	23.2 \pm 2.6 years	23.4 \pm 2.7 years	>0.05
Primigravida:multiparavida	131:19	129:21	>0.05
Booked:unbooked	84:66	78:72	>0.05

Table 2: Distribution of cases according to severity of pain by visual analogue score (VAS) for post episiotomy pain at various times.

Visual analogue score	Group A (RAPG - 910)		Group B (chromic catgut)		P value
	Mean	SD	Mean	SD	
At 24 hours	5.84	0.77	5.93	0.83	0.34
At 48 hours	5.46	0.62	5.86	0.71	0.04
Day 7-10	0.73	0.12	1.20	0.18	0.01
At 6 weeks	0.14	0.05	0.23	0.08	0.03

Table 3: Distribution of cases, as per need of analgesics for pain, at various times.

Analgesic requirement		Group A (RAPG - 910)	Group B (chromic catgut)	Total	P value
		N (%)	N (%)		
0-24 hours	Required	145 (96.7)	148 (98.7)	293 (97.7)	0.25
	Not required	5 (3.3)	2 (1.3)	7 (2.3)	
24-48 hours	Required	142 (94.7)	146 (97.3)	288 (96)	0.24
	Not required	8 (5.3)	4 (2.7)	12 (4)	
Day 7-10	Required	62 (41.3)	97 (64.7)	159 (53)	0.001
	Not required	88 (58.7)	53 (35.3)	141 (47)	
6 weeks	Required	5 (3.3)	14 (9.3)	19 (6.3)	0.03
	Not required	145 (96.7)	136 (90.7)	281 (93.7)	

Table 4: Distribution of cases according to hematoma formation at suture site.

Hematoma formation, present at	Group A (RAPG - 910)	Group B (chromic catgut)	Total	P value
	N (%)	N (%)		
≤ 24 hours	2 (1.3)	3 (2)	5 (1.7)	0.65
Between 24 - 48 hours	1 (0.7)	2 (1.3)	3 (1)	0.56
Day 7 - 10	1 (0.7)	1 (0.7)	2 (0.7)	0.99
6 weeks	0 (0)	0 (0)	0 (0)	-
Total	4 (2.7)	6 (4)	10 (3.3)	0.52

Number of cases with need of analgesics for pain relief were significantly higher in group B than group A at day 7-10 and 6 weeks; the difference was statistically significant ($p<0.05$). At various post episiotomy times, when examined; hematoma formation incidence was slightly higher in group B; the difference was statistically insignificant ($p>0.05$). 1.3% cases in group A and 2% cases in group B, had hematoma formation at ≤ 24 hours; 0.7% cases in group A and 1.3% cases in group B, had

hematoma formation within 24-48 hours; while 0.7% cases of group A and 0.7% of group B had hematoma formation at day 7-10. Hematoma formation was not seen in any group at 6 week. At various post episiotomy times, when examined; it was found that occurrence of wound infection was always higher in group-B, but the difference was statistically insignificant in first 48 hours & at 6 weeks; while, it was significant at day 7-10. As, 1.3% cases in group A and 3.3% cases in group B had

wound infection in first 48 hours; 2.7% cases of group A and 8.7% of group B had infected wound at day 7-10; and 0.7% cases of group A and 2% of group B had infected wound at 6 weeks. 0.7% cases in group and 1.3% cases in group B had complaint of wound gaping; and 0.7% cases

of group A, and 1.3% cases of group B required re-suturing for wound gaping. Use of chromic catgut was associated with higher incidence of wound gaping and need of re-suturing as compared to RAPG-910; but, the difference was statistically insignificant ($p>0.05$).

Table 5: Distribution of cases as per presence of wound infection at various times.

Wound infection Present at	Group A (RAPG - 910) N (%)	Group B (chromic catgut) N (%)	Total	P value
First 48 hours	2 (1.3)	5 (3.3)	7 (2.3)	0.25
Between Day 7 - 10	4 (2.7)	13 (8.7)	17 (5.7)	0.02
6 weeks	1 (0.7)	3 (2)	4 (1.3)	0.31

Table 6: Cases as per incidence of wound gaping& need of re-suturing.

Condition of wound	Group A (RAPG - 910) N (%)	Group B (chromic catgut) N (%)	Total	P value
Wound gaping				
Present	1 (0.7)	2 (1.3)	3 (1)	0.56
Absent	149 (99.3)	148 (98.7)	297 (99)	
Re-suturing required				
Yes	1 (0.7)	2 (1.3)	3 (1)	0.56
No	149 (99.3)	148 (98.7)	297 (99)	

DISCUSSION

Episiotomy has maternal and fetal benefits but at the cost of sum postpartum morbidity which depends on a number of variables. Out of these variables one important factor remains the suture material used in episiotomy repair. The choice of suture material depends on its inherent characteristics like absorbable or non-absorbable, tensile strength, knot security and tissue reactivity. Selection of appropriate suture material for use in episiotomy repair has been a topic of debate and study among the practitioners. So, this study was purposed to study suture materials, namely rapidly absorbing polyglactin 910 (RAPG-910) and chromic catgut; in relation to post episiotomy complications and maternal morbidity like perineal pain, analgesic requirement, hematoma formation, wound gaping, wound infections, wound healing and dyspareunia; when used for episiotomy repair. And this discussion aims to analyze and compare the findings of our study with various other relevant studies. In current study, use of chromic catgut was associated with a higher severity of post episiotomy pain at 48 hours, day 7-10 and 6 weeks. The reported mean values of VAS at 48 hours (5.46 ± 0.62 v/s 5.86 ± 0.71), day 7-10 (0.73 ± 0.12 v/s 1.20 ± 0.18) and 6 weeks (0.14 ± 0.05 v/s 0.23 ± 0.08) were higher in group-B with a statistically significant difference between two groups ($p<0.05$). The difference in severity of pain was less appreciated at 24 hours as VAS values in group A (5.84 ± 0.77) and group B (5.93 ± 0.83) had insignificant difference ($p>0.05$).

In current study, in first 24 hours of post episiotomy, 96.7% cases in group A and 98.7% cases in group B required analgesics for pain relief. Between 24-48 hours 94.7% cases of group A and 97.3% cases of group B required analgesics for pain. Number (%) of cases who

needed analgesics for pain relief at ≤ 24 hours and between 24-48 hours were almost similar in both study groups ($p>0.05$). In contrast, 41.3% cases in group A and 64.7% cases in group B required analgesic at day 7-10. 3.3% cases of group A and 9.3% cases of group B required analgesics at 6 weeks. Number (%) of cases who needed analgesics for pain relief was significantly higher in group-B than group-A at day 7-10 & 6 weeks ($p<0.05$). As per findings of study, Seehra et al concluded that on day 7, only 21.4% of cases required analgesics in contrast to 54.3% of controls ($p<0.001$).⁴ These findings were similar to our study. In current study, the incidence of post episiotomy pain was comparable between 24-48 hours for group A and group B, but the severity and required dose of analgesics for pain was significantly higher in chromic catgut group ($p<0.001$). In group A (RAPG-910), mean value for analgesics tablets required per case per day was 1.86 ± 0.38 tablets while in group B (catgut), it was 2.14 ± 0.46 tablets per case per day. The difference was statistically significant.

The required dose of analgesics for pain relief was significantly higher in group B as compared to group-A at day 7-10 also ($p<0.001$). In group A, 1.67 ± 0.24 tablets per case per day and in group B 1.94 ± 0.31 tablets per case per day were required. Likewise study, Bose et al and Abdullah et al concluded that the requirement of analgesia in vicrylrapide group was significantly lower than chromic catgut group.^{1,5} Similar to our study, Deshpande et al reported that use of RAPG-910 required significantly less analgesia as compared to chromic catgut after 1st day, 2nd day, 3rd day, 10th -14th days & 42 days.⁶ Similar findings were reported in the RCT by Leroux et al where the mean consumption of analgesics in the early postpartum period was significantly more in the chromic catgut group ($p<0.01$).⁷ In current study, use

of chromic catgut was associated with a higher incidence of hematoma formation but the difference was statistically insignificant ($p>0.05$). At ≤ 24 hours 1.3% cases in group A and 2% cases in group B had hematoma formation. 0.7% cases in group A and 1.3% cases in group B had hematoma formation between 24-48 hours. 0.7% cases of group A and group B had hematoma detected at day 7-10. Hematoma formation was not seen at 6 week in either group. In current study, use of chromic catgut was associated with a higher incidence of wound infection at day 7-10. 2.7% cases of group A and 8.7% of group B had infected wound, the difference was statistically significant ($p<0.05$). The incidence of wound infection in first 48 hours and 6 weeks was comparable in both study groups and the difference was statistically insignificant ($p>0.05$). The findings of our study were almost similar to those of Bharathi et al where wound infection was found in 4% of the cases in the chromic catgut group and it was absent in vicrylrapide group ($p<0.05$).²

CONCLUSION

To conclude, rapidly absorbing polyglactin 910 was better than chromic catgut in relation to post episiotomy complications and maternal morbidity with a significantly lesser incidence and severity of post episiotomy pain, lesser dose of analgesia required, lesser wound gaping and infection, better wound healing, faster suture reabsorption.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Singh P, Soni M, Verma N. A prospective randomized comparative study of rapidly absorbing polyglactin 910 versus chromic catgut for episiotomy repair at tertiary care hospital Bikaner, Rajasthan. *Int J Reprod Contracept Obstet Gynecol* 2021;10:3445-9.